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Relieving Acute Manic
& Mixed Symptoms of Bipolar I Disorders...

Without Inducing
Weight-Gain.¹

Equetro® References

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**EQUETRO VIRTUAL
ADVISORY BOARD**

Product Information, Clinical Data, and Downloadable Patient Education Materials for Healthcare Professionals

To Help You Prescribe Equetro® (carbamazepine) Extended-Release Capsules to Treat the Acute Manic & Mixed Episodes of Bipolar I Disorder—without weight-gain¹

Please [click here](#) to review the Equetro® references.

WARNING

Important Safety Information about Equetro® (carbamazepine) Extended-Release Capsules

Warning Serious Dermatologic Reactions and HLA-B*1502 Allele

Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS), have been reported during treatment with carbamazepine. These reactions are estimated to occur in 1 to 6 per 10,000 new users in countries with mainly caucasian populations, but the risk in some Asian countries is estimated to be about 10 times higher. Studies in patients of Chinese ancestry have found a strong association between the risk of developing SJS/TEN and the presence of HLA-B*1502, an inherited allelic variant of the HLA-B gene. HLA-B*1502 is found almost exclusively in patients with ancestry across broad areas of Asia. Patients with ancestry in genetically at-risk populations should be screened for the presence of HLA-B*1502 prior to initiating treatment with Equetro® (carbamazepine) Extended-Release Capsules. Patients testing positive for the allele should not be treated with Equetro® (carbamazepine) Extended-Release Capsules unless the benefit clearly outweighs the risk (see warnings and precautions, laboratory tests).

Aplastic Anemia and Agranulocytosis

Aplastic Anemia and Agranulocytosis have been reported in association with the use of carbamazepine. Data from a population based case-control study demonstrate that the risk of developing these reactions is 5–8 times greater than in the general population. However, the overall risk of these reactions in the untreated general population is low, approximately six patients per one million population per year for Agranulocytosis and two patients per one million population per year for Aplastic Anemia.

Although reports of transient or persistent decreased platelet or white blood cell counts are not uncommon in association with the use of carbamazepine, data are not available to estimate accurately their incidence or outcome. However, the vast majority of the cases of leukopenia have not progressed to the more serious conditions of Aplastic Anemia or Agranulocytosis.

Because of the very low incidence of Agranulocytosis and Aplastic Anemia, the vast majority of minor hematologic changes observed in monitoring of patients on carbamazepine are unlikely to signal the occurrence of either abnormality. Nonetheless, complete pretreatment hematological testing should be obtained as a baseline. If a patient in the course of treatment exhibits low or decreased white blood cell or platelet counts, the patient should be monitored closely. Discontinuation of the drug should be considered if any evidence of significant bone marrow depression develops.

Anti-epileptic drugs (AEDs), including Equetro®, may increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence of worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

PLEASE SEE [FULL PRESCRIBING INFORMATION](#) INCLUDING CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, AND BOXED WARNING FOR ADDITIONAL SAFETY INFORMATION ON EQUETRO® (CARBAMAZEPINE) EXTENDED-RELEASE CAPSULES.

Please see [Medication Guide](#) for additional information.

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[Clinical Information](#)

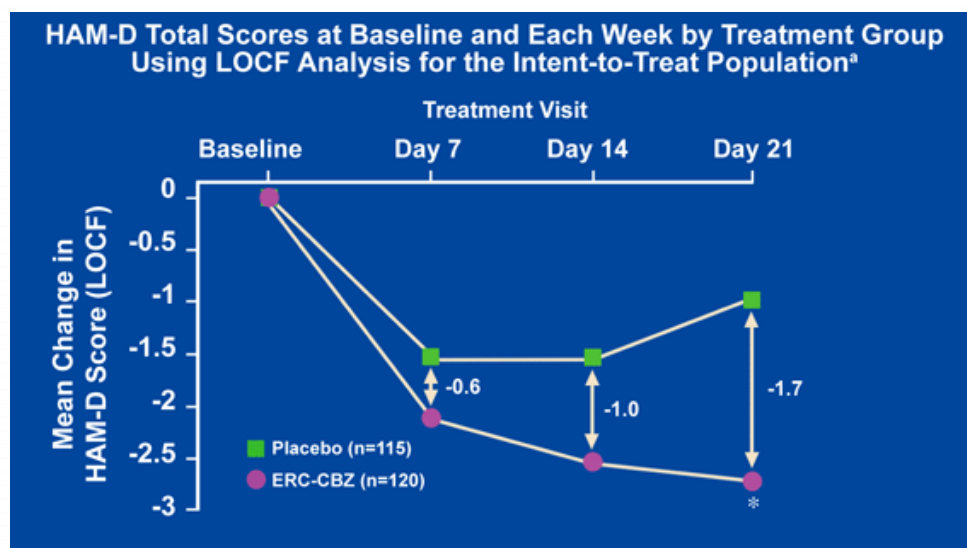
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The HAM-D SCALE reveals that Bipolar I Patients treated with Equetro® (carbamazepine) Extended-Release Capsules showed no worsening of depression⁵



^aIn the ERC-CBZ group, HAM-D scores were 9.60 at baseline and 6.88 at endpoint; in the placebo group, scores were 9.45 at baseline and 8.47 at endpoint.

*p<.01 compared with placebo following analysis of covariance with baseline score as covariate.

Abbreviations: ERC-CBZ=extended-release carbamazepine capsules, HAM-D=Hamilton Rating Scale for Depression, LOCF=last observation carried forward

[Click here to view data confirming](#)

Efficacy in Acute Manic & Mixed Symptoms
with Equetro® (carbamazepine) Extended-Release
Capsules Therapy

Equetro® References

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Minimal Effect on Weight
with Equetro® (carbamazepine) Extended-Release
Capsules Therapy

Equetro® (carbamazepine) Extended-Release Capsules is the only carbamazepine-containing product that has gained FDA approval for treatment of acute manic and mixed symptoms of Bipolar I Disorder.

REMINDER: Equetro® (carbamazepine) Extended-Release Capsules contains carbamazepine. **Please ensure patient is not taking any other form of carbamazepine.**

The BATHROOM SCALE reveals that Equetro® (carbamazepine) Extended-Release Capsules therapy has minimal effect on weight⁴

--as observed in short-term and long-term evaluations

TWO 3-WEEK PIVOTAL TRIALS (n=208) ³		
	Equetro®	Placebo
Mean change in weight	+2.3 lb*	0.1 lb
• Low percentage of patients with clinically significant weight gain (Equetro® 5.3%** , placebo 0.95%)		
6-MONTH, OPEN-LABEL EXTENSION STUDY [†] (n=83) ⁴		
Mean change in weight.....	Equetro -0.9 lb	
• No patient had clinically significant weight gain.		

*p<0.001 vs. placebo

**p= 0.0112 vs. placebo

[†]Study completers, n =24. Clinically significant weight gain was defined as an increase from baseline of ≥7%. Reported data reflect weight change at endpoint (LOCF).

No Bipolar I patients showed significant weight gain in the long term evaluations of Equetro® (carbamazepine) Extended-Release Capsules. Average 6-month weight change was -0.9 pounds.

Click here to view data confirming

Efficacy in Acute Manic & Mixed Symptoms
with Equetro® (carbamazepine) Extended-Release
Capsules Therapy

No Worsening of Depression
with Equetro® (carbamazepine) Extended-Release
Capsules Therapy

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Please see [Medication Guide](#) for additional information.

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